REMARKS/ARGUMENTS

In response to the Office Action of May 31, 2005, Applicants have amended the claims, which when considered with the following remarks, is deemed to place the present application in condition for allowance. Favorable consideration of all pending claims is respectfully requested.

Claims 6-10 have been withdrawn by the Examiner as allegedly drawn to a non-elected invention. In the listing of claims submitted herewith, such claims are indicated as withdrawn. The Examiner has indicated on page 4 of the Office Action that the preliminary amendment filed in this case was not entered due to all claims not being presented. The listing of claims submitted herewith lists presently pending claims 1-10 with the relevant status identifiers in parentheses. In addition, the specification has been amended to provide a cross reference to related applications.

Claims 1-2 and 4-5 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly directed to non-enabled subject matter. It is the position of the Examiner that the specification is enabled for cyclosporins and lactam macrolides, but does not provide enablement for a difficultly soluble active agent as recited in claim 1, and macrolide as recited in claim 2. In response to the rejection and in order to advance prosecution of this application, claim 1 has been amended to recite in relevant part: " [a] microemulsion pre-concentrate comprising a difficultly soluble active agent selected from a cyclosporin or a lactam macrolide". Claim 2 has been canceled without prejudice. Applicants reserve the right to prosecute subject matter recited by the claims prior to this amendment in one or more continuation applications. In view of the amendments to claim 1, withdrawal of the rejection of claims 1-2 and 4-5 under the enablement provision of 35 U.S.C. § 112, first paragraph, is warranted.

Claim 4 has been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention. In particular, the Examiner has objected to the terminology "in any preceding claim." As presently amended, claim 4 depends from claim 1 or 3. Withdrawal of the rejection of claim 4 under 35 U.S.C. § 112, second paragraph is therefore respectfully requested.

Claim 5 has been objected to under 37 C.F.R.§ 1.75(c) as allegedly in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. As presently amended, claim 5 depends only from claim 1 or 3, neither of which claims are multiple dependent claims. Withdrawal of the objection to claim 5 under 37 C.F.R. § 1.75(c) is therefore respectfully requested.

Claims 1-3 and 5 have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Woo (U.S. Patent No. 5,603,951), which issued on February 18, 1997. 35 U.S.C. § 102(b) provides:

> A person shall be entitled to a patent unless-
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

The present application is a continuation application of U.S. Serial No. 09/668,677, filed September 22, 2000, which was a continuation of U.S. Serial No. 08/737, 774, filed November 25, 1996, which was a U.S. national phase (section 371) application of International Application PCT/EP95/04187, having an international filing date of October 25, 1995.

35 U.S.C. § 363 provides:

> An international application designating the United States shall have the effect, from its international filing date under article 11 of the treaty, of a national application for patent regularly filed in the Patent and Trademark office except as other wise provided in section 102(e) of this title.

As international application PCT/EP95/04187 designated the United States, under 35 U.S.C.§ 363, the international filing date also serves as the date of application for patent in the U.S. under 35 U.S.C.§ 102(b). Since Woo was not patented or described in a printed publication more than one year prior to the international filing date PCT/EP95/04187, Woo is not a proper reference under 35 U.S.C.§ 102(b). Withdrawal of the rejection of claims 1-3 and 5 under 35 U.S.C. § 102(b) is therefore respectfully requested.

Claims 1-3 and 5 have been rejected under 35 U.S.C.§ 103(a) as allegedly unpatentable over Fricker et al (U.S. Patent No. 5,932,243) in view of Woo (U.S. Patent No. 5,603,951).

Since Fricker et al. issued on August 3, 1999, which date is not more than one year prior to October 25, 1995, and based on those sections of the patent statute cited above, Fricker et al. is not available as a reference under 35 U.S.C.§ 102(b) for purposes of section 103(a) analysis.

35 U.S.C.§ 103 (c) provides the following:

> (c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

STATEMENT CONCERNING COMMON OWNERSHIP

The undersigned hereby states that the present application (U.S. Serial No. 09/738,104) and U.S. Patent No. 5,932,243 ("Fricker" et al.) were, at the time the invention of the present application was made, owned by, or subject to, an obligation of assignment to the same corporate entity, Sandoz.

According to the "Guidelines Setting Forth a Modified Policy Concerning the Evidence of Common Ownership, or an Obligation of Assignment to the Same Person, as Required by 35 U.S.C.§ 103(c)," 1241 O.G. 96 (December 26, 2000), the above statement alone is sufficient evidence to disqualify Fricker et al. from being used in a rejection under 35 U.S.C.§ 103(a) against the claims of the present application.

For the Examiner's convenience however, provided herewith at Exhibit A, is a copy of PCT/EP95/04187. As discussed above, the grandparent application to the present application was a 371 application of PCT/EP95/04187. As may be seen from the cover of PCT/EP95/04187, the owner of the invention at the time the invention of the present application was made, was Sandoz.

Also for the convenience of the Examiner, Applicants provide at Exhibit B, German Patent Publication DE 4418115 A1, a foreign counterpart application to the cited reference, Fricker et al (U.S. Patent No.5,932,243). As indicated on the cover of DE 4418115 A1, the owner of the invention described therein, was Sandoz. The cover of Fricker et al. indicates Novartis AG, as the assignee since by the time an assignment was recorded in the U.S. PTO in the application which matured into Fricker et al., Novartis owned the invention. As indicated in the foreign counterpart application provided at Exhibit B however, the invention disclosed in Fricker et al was owned by Sandoz at the relevant time.

In addition, Applicants rely on the benefit of previously filed foreign applications to establish an effective filing date earlier than that of the secondary reference, Woo (U.S. Patent No. 5,603,951).

35 U.S.C.§ 365(b) provides the following:

> (b) In accordance with the conditions and requirements of section 119(a) of this title and the treaty and the Regulations, an international application designating the United States shall be entitled to the right of priority based on a prior foreign application, or a prior international

application designating at least one country other than the United States.

International application PCT/EP95/04187 is therefore entitled to a right of priority based on prior GB applications: 9421613.2; 9422084.5; 9425353.1; and 9517133.6, all of which applications were filed prior to the U.S. application which matured into Woo (U.S. Patent No. 5,603,951). Thus, Applicants have antedated Woo by relying on previously filed foreign applications to establish an effective filing date earlier than the U.S. filing date of Woo, a practice approved by the Federal Circuit. *See In re Gostelii,* 872 F.2d 1008, 10 USPQ2d 1614,1616 (Federal Circuit 1989). Since neither Fricker et al., nor Woo is available as a reference under 35 U.S.C.§ 103(a), withdrawal of the rejection of claims 1-3 and 5 under this section of the statute is warranted.

In view of the foregoing remarks and amendments, it is firmly believed that the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

Ann R. Pokalsky
Reg. No. 34,697
Attorney for Applicants

Novartis
Corporate Intellectual Property
One Health Plaza, Building 430
East Hanover, NJ 07936-1080
(862) 778-7859

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